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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,449

09/09/2003

Mark A. Reiley

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,449	<b>Applicant(s)</b> REILEY, MARK A.	
	<b>Examiner</b> CHRISTOPHER D. PRONE	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20,22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20,22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/24/09 10/6/08  
4/25/08 11/05/07 8/14/07.

## **DETAILED ACTION**

### ***Status of the Claims***

Currently claims 1-20, 22, 24 are pending for consideration, claims 21 and 23 are cancelled, and claims 25-27 remain withdrawn from consideration.

### ***Response to Arguments***

Applicant's arguments filed 8/7/07 have been fully considered but they are not persuasive.

With respect to the outstanding rejection under 35 USC 112, applicant's representative is correct, in that, they were only directed toward claims 2-7 and 20. In regards to claims 2-4 the applicant better defined the location of the implant but failed to define what orientation is intended. The directions superior, anterior, and posterior are all relative to the operator's or viewer's orientation with respect to the subject. In regards to claims 5-7 they remain indefinite because the claims are directed at an intended use requiring an adaptation but no structure from the elected embodiment is defined that would enable one of ordinary skill within the art to be apprised of the scope of the invention. The applicant is advised to better define structural components. The rejection over claim 20 has been overcome, but claim 19 from which it depends appears to be indefinite because it fails to further limit the independent claim, which is described in further detail below.

The rejection to the claims under 35 USC 102 over any of Wall, Zang, Homsy and Morgan as comprising each structural element as broadly claimed is still maintained by the examiner. Applicant argues that the every feature recited by the claims is not disclosed by the references or record and that each reference was not specifically outlined. The examiner has reproduced claim 1 below emphasizing only the required structural components

1. (Original) A prosthesis to replace all or a portion of a natural facet joint on a vertebral body comprising a prosthesis body accommodating fixation to the vertebral body at or near a pedicle and without support by a lamina, the prosthesis body including a fastening element installed within the vertebral body at or near a pedicle, and an artificial facet joint structure carried by the prosthesis body at a location spaced from the fastening element, the artificial facet joint structure being adapted and configured to replace all or a portion of a natural facet joint.

Examiner maintains as broadly worded the cited prior art independently show a prosthesis comprising a body including a fastening element that is to be installed within a bony body including an artificial facet joint structure carried by the body spaced from the fastening element where the facet joint is configured to replace all or a portion of the natural joint. By viewing the figures of each reference it is abundantly clear what can be considered the body, the fastening element, and the spaced apart joint.

The examiner admits that the recitation of the prosthesis to be used to replace all or a portion of the natural facet joint on a vertebral body is not specifically disclosed in any of the applied references. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the examiner's contention that the devices of the applied references do set forth structure that is capable of performing the intended function, i.e. a prosthesis to replace all or a portion of a natural facet joint on a vertebral body. Because the art of record contains all the structure recited within the claims and has an overall general similar structure it is inherent that they could function as required by the claims, which the applicant has failed to point out any factual reasoning to the contrary. Applicant is advised to present factual evidence, not opinions to dismiss the art of record from being able to perform as claimed.

***Claim Rejections - 35 USC § 112***

Claims 2-7, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 are indefinite. It is not clear as to what frame of reference is being used to establish the location of the sub-elements of the claims. It appears

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applicant is attempting to define the relationship of the prosthesis with respect to the various axes of the body.

Claims 5-7 the term "adapted and configured" in the claims is a relative term which renders the claim indefinite. The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language absent structural features relies solely on a functional use (ie. to replace a certain anatomical feature. The elected invention is directed to figure 36. Claim 1 positively sets forth structural elements of a body and a facet joint structure. However, claim 5 fails to positively set forth structure that would function after the removal of at least some of the facet joint from the vertebral body. It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some of the facet joint. Since there is only one embodiment, figure 36, it is not clear how the structure of this one embodiment differs from each other as required in each of claims 5-7.

Claim 19 is indefinite because it does not further define independent claim 1 from which it depends. The claim just requires that the joint is made of at least on prosthetic material, which is inherent because the joint could not be made out of air. It has to be made of a material. Furthermore in claim 19 the phrase prosthetic material is not limiting because any and all materials can be considered prosthetic materials.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 18, 19, 20, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Zang et al [5,314,486], Wall [4,633,722], Homsy et al [4,778,472] and Morgan [4,917,701].

Each prior art individually discloses a prosthesis comprising a fastening element, and an artificial joint structure carried by the fastening element. While the prosthesis of each prior art is intended for replacement of another type of joints, the structure as broadly claimed is fully met by each of the applied prosthesis. Each prosthesis is structurally similar to that as illustrated by applicant and therefor, examiner contends that each device is capable of performing the function of replacing all or a portion of the natural facet joint.

Claims 2-4, the claim as worded may be interpreted in the manner by which the prosthesis is attached in vivo. (ie. method of using the prosthesis, where the placement of the device would position the fastening element superior to the joint structure.)



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Claim 5, in so far as definite, the placement of the prior art joint according to claim 1 would yield in a facet joint structure that articulates with a portion of the joint structure of the adjoining vertebral body.

Claims 6, in so far as definite, the placement of the prior art joint according to claim 1 would yield in a facet joint structure that replaces a cephalad portion of the natural facet joint.

Claim 7, in so far as definite, the placement of the prior art joint according to claim 1 would yield in a facet joint structure that replaces a cephalad portion of the natural facet joint and articulate with a caudal portion of a facet joint.

Claim 8, see each joint structure in the respective prior art as applied in claim 1 supra.

Claims 10-14 and 18 see prosthesis of Zang, et al. One of the fastening elements or the facet joint structure of Zang et al is illustrated to be one piece; the other of the element is shown to be formed of two pieces with a tapered connection.

Claims 19 and 20, see materials as set forth in each reference as applied in claim 1.

Claims 22 and 24, see Zang, et al wherein the prosthesis is fabricated from selected biocompatible materials including titanium, cobalt chrome and may be fastened to the bone by with roughen surface providing a bone in-growth surface medium.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al as applied to claim 1 above, and further in view of Carignan, et al [4,955,916].

The insert of Zang et al is mechanically fixed to the fastening element. Carignan et al teaches forming each cooperating sub-elements of the total joint of plural pieces for better flexibility and adaptability to meet the structural constraints of the individual patient's bone structure. To form each sub-element of Zang et al of a multiple piece connection would have been obvious from the teachings of Carignan.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al as applied to claim 1 above, and further in view of Hamilton et al [5,314,492].

.Zang et al discloses forming one of the cooperating sub-elements of the total joint of plural pieces for better flexibility and adaptability to meet the structural constraints of the individual patient's bone structure. While Zang et al does not use adhesive in combination with the tapered connection, Hamilton et al

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teaches using both fixation means for providing a secure connection between the sub-elements. To add adhesive to the tapered surfaces of Zang et al to ensure a more secure connection between the two components would have been obvious to one with ordinary skill in the art from the teachings of Hamilton et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone  
Examiner  
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/  
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